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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,770	11/19/2001	Steven Leigh	2001-1087A	7884

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 03/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/890,770

Applicant(s)

LEIGH ET AL.

Examiner

Gollamudi S Kishore, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-15 and 17-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-15 and 17-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

RCE dated 2-26-04 is acknowledged.

Claims included in the prosecution are 12-15 and 17-22.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 12-15 and 17-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Touitou (5,716,638) or Ribier (5,614,215) in view of the references of Mehta (5,811,119), Ganter (5,635,206), GB 2 002 319 by themselves or in combination.

Touitou while disclosing phospholipid-containing compositions for application to the skin teaches the use of a combination of caffeine and salicylate (note the abstract and Example XVII on col. 10).

Ribier while disclosing liposomal compositions for application to the skin teaches that a combination of a keratolytic agent such as salicylic acid along with a liporegulating agent such as caffeine could be used (note the abstract, col. 6, lines 56-60).

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What is lacking in these references is the teaching of formulating the composition in the form of a powder, which upon hydration forms liposomal structures.

Mehta discloses powders containing phospholipids and retinoic acid. The powder upon reconstitution forms liposomes (note the abstract and examples, example 1 in particular).

Ganter teaches that liposomal and proliposomal preparations containing the phospholipid can be prepared in a powder form for easy storage (abstract, col. 2, line 15 through col. 3, line 34 and examples).

GB teaches that liposomes can be dehydrated to form a stable powder, which can be stored for a long period of time and can be reconstituted into liposomes again (abstract).

The dehydration of the liposomal compositions containing a hydroxy-acid and caffeine (a xanthine compound) taught by Touitou or Ribier would have been obvious to one of ordinary skill in the art since the references of Mehta, Ganter, and GB show that the liposomes or proliposomal compositions can be prepared in the form of a stable powder for prolonged storage.

Applicant's amendment to the claims reciting 'consisting essentially of' and arguments that instant claims exclude the aliphatic alcohol in Touitou and two separate dispersions in Ribier are noted. With regard to Touitou, the examiner points out that when the liposomes of Touitou are converted into powders based on the suggestion provided by the references of Mehta, Ganter and GB, the alcohol would have evaporated. With regard to Ribier, the examiner points out that Ribier teaches two types

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of liposome populations in the compositions for the advantage, namely, one population to penetrate deep into the skin and one to act on the skin and it would have been obvious to one of ordinary skill in the art to prepare a single liposome composition if the advantages provided by the second population of liposomes are not needed.

3. Claims 12-15 and 17-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Roux (6,103,259) or Hayward (5,585,109) in view of either Touitou (5,716,638) or Ribier (5,614,215), further in combination with Mehta or Ganter or GB cited above.

Roux discloses liposomal preparations containing alpha hydroxy acids such as salicylic acid (note the abstract, col. 2, line 54 through col. 5, line 3). Roux however, does not teach the addition of a xanthine compound. Roux also does not teach the preparation of liposomes in the form of a powder.

Hayward similarly discloses liposomal compositions containing salicylic acid (note the abstract, and examples). Hayward however, does not teach the preparation of liposomes in the form of a powder and Hayward does not teach the inclusion of a xanthine compound along with salicylic acid.

Touitou while disclosing phospholipid-containing compositions for application to the skin teaches the use of a combination of caffeine and salicylate (note the abstract and Example XVII on col. 10).

Ribier while disclosing liposomal compositions for application to the skin teaches that a combination of a keratolytic agent such as salicylic acid along with a

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liporegulating agent such as caffeine could be used (note the abstract, col. 6, lines 56-60).

The teachings of Mehta, Ganter, and GB have been discussed above.

The inclusion of caffeine in the compositions containing a salicylic acid of Roux or Hayward would have been obvious to one of ordinary skill in the art since the references of Touitou, and Hayward show the routine practice in the art of using a combination of salicylate and a Xanthine such as caffeine; one of ordinary skill in the art would expect the benefits of both agents from the resulting combination. The dehydration of the compositions to form powders would have been obvious to one of ordinary skill in the art since the references of Mehta, Ganter, and GB show that the liposomes or proliposomal compositions can be prepared in the form of a stable powder for prolonged storage.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, PhD whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 1234.



Gollamudi S Kishore, PhD
Primary Examiner
Art Unit 1615

GSK